PB87-235016

Guidance for the Reregistration of Pesticide Products Containing Tebuthiuron as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Jul 87

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB87-235016/AS

4. Title and Subtitle

Guidance for the Registration of Pesticide Products Containing TEBUTHIURON as the Active Ingredient.

5. Report Date ISSUED July 1987

6.

7. Author(s)

EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No. 540/RS-87- 219

9. Performing Organization Name and Address

US Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, SW
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.

(C)

(G)

12. Sponsoring Organization Name and Address

Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how th register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:

Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 117

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

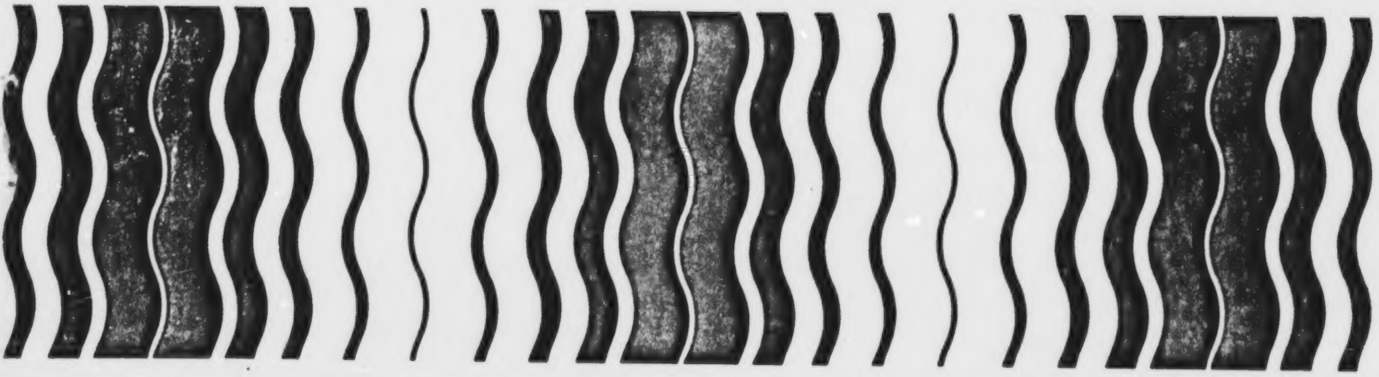
July 1987

Pesticides

PB87-235016

EPA

Guidance for the Reregistration of Pesticide Products Containing Tebuthiuron as the Active Ingredient



REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA 22161

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

Tebuthiuron

AS THE ACTIVE INGREDIENT

OPP NUMBER 105501

CAS NUMBER 34014-18-1

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

APPENDICES

I. DATA APPENDICES

Guide to Tables

Table A

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Formulator's Exemption Statement

TABLE OF CONTENTS

Glossary of Terms and Abbreviation iii

I. Introduction 1

II. Chemical Covered by this Standard 4
  A. Description of Chemical
  B. Use Profile
  C. Chemical Structures

III. Agency Assessment 8
  A. Summary
  B. Preliminary Risk Assessment
  C. Other Science Findings
  D. Tolerance Reassessment

IV. Regulatory Position and Rationale 17
  A. Regulatory Positions and Rationales
  B. Criteria for Registration
  C. Acceptable Ranges and Limits
  D. Required Labeling

V. Products Subject to this Standard 26

VI. Requirement for Submission of Generic Data 28
  A. What are generic data?
  B. Who must submit generic data?
  C. What generic data must be submitted?
  D. How to comply with DCI requirements
  E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data
  F. Procedures for requesting a change in testing protocol
  G. Procedures for requesting extensions of time
  H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice
  I. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submission of Revised Labeling 35

VIII. Instructions for Submission 35
  A. Manufacturing use products (sole active)
  B. Manufacturing use products (multiple active)
  C. End use products
  D. Addresses

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI: Acceptable Daily Intake

a.i.: Active ingredient

CAS : Chemical Abstract Services (number)

CSF: Confidential Statement of Formula

EPA: The Environmental Protection Agency, also "the Agency"

F_1, F_2: Refers to the generations in a multi-generation study

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

LC_{50}: (median lethal concentration) a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).

LD_{50}: (median lethal dose) a statistically derived single dose that can be expected to cause death in 50% of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

LEL: Lowest Effect Level

MPI: Maximum Permissible Intake

MRID: Master Record Indentification (number) - EPA's system of tracking studies used in support of registrations.

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level

OPP: The Office of Pesticide Programs

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

Technical: Active ingredient as manufactured

MATC: Maximum Allowable Toxic Concentration

mg/kg bwt/day: milogram per kilogram of body weight per day

mbyp: meat by product

Kd: Soil-water adsorption partition cofficients

Screen: A process through which EAB asseses the Leaching potential of a pesticide

EL-103: Tebuthiuron Technical

EPs: End-Use-Products

2AA: 2-Amino anthracin

AmAc: 9- Amino aindine

MMNG: N-Methyl N'Nitroguanidine

2NF: 2-Nitroflourene

> : greater than

< : less than

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

---

[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard.

Common Name: Tebuthiuron

Chemical Name: N-[5-(1,1-dimethylethyl)-1,3,4-thia diazol-2-yl]- N,N'dimethylurea

CASE No.: GS 0054

OPP Shaughnessy No.: 105501

Empirical Formula: $C_9H_{16}N_4OS$

Year of Initial Registration: 1974

B. Use Profile

Type of Pesticide: A relatively nonselective, soil actived herbicide for the control of broadleaf weeds, grasses and brush in noncrop areas, and for spot treatment of woody brush on rangelands. It is readily absorbed through roots of broadleaf weeds, grasses and brush.

Registered uses: Terrestrial food crop (rangelands and pastures), noncrop areas (airport runways, fencerows, firebreaks, industrials sites, paved surface), and aquatic non-crop (ditchbanks).

Predominant Uses: Terrestrial noncrop areas

Method of Application: Applied as broadcast or band by ground or aerial equipment, spot treatment, drop zone or drip zone treatment or grid pattern treatment.

Formulation: 95% (a.i.) technical; 1%, 2%, 3%, & 5% granular; 10%, 13.8%, 15.2%, 20%, 30.5% , 40% pelleted/tableted; 80% wettable powder; 85% flowable concentrate; and 0.36% soluble concentrate/liquid.

Mode of activity: Photosynthesis inhibitor

III. AGENCY ASSESSMENT

A. Summary

The Agency has reviewed all of the data submitted to support the registration of tebuthiuron. Based on the review of these data, the Agency has reached the following conclusions:

1. Tebuthiuron is only slightly acutely toxic by inhalation in rats and is in toxicity category III.

2. A rat multigeneration study showed no adverse reproductive effects.

3. Tebuthiuron did not cause DNA damage in bacteria and was only slightly mutagenic in a mouse lymphoma assay.

4. The Agency is concerned about the potential for ground water contamination by tebuthiuron. The Agency has determined that additional data are needed to fully characterize the potential for tebuthiuron to enter ground water.

5. The use of tebuthiuron on rangeland and pastureland will pose a hazard to endangered species.

6. As a result of this review, the agency has identified missing data necessary to evaluate the environmental and human risks associated with the use of tebuthiuron. These data must be developed in order to maintain registration of products or to register new products containing tebuthiuron. A summary of these data gaps appear in figure 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

Figure 1

Summary Of Data Gaps

Tebuthiuron

§158.120-Product Chemistry

§158.125 Residue Chemistry:

171-4 Nature of the Residue (Plant & Animal Metabolism)
171-4 Residue Analytical Methods
171-4 Storage Stability
171-4 Residue Studies on crops, Processed Food/Feed Commodities

§158.135 Toxicology:

81-1	Acute Oral-Rat
81-2	Acute Dermal
81-4	Eye Irritation-Rabbit
81-5	Dermal Irrition-Rabbit
81-6	Dermal Sensitization Guinea Pig
83-1	Chronic Toxicity (Rodent)
83-2	Oncogenicity Study (Two Species)
83-3	Teratogenicity (Two Species)
84-2	Mutagenicity
85-1	Metabolism

§158.130 Environmental Fate

161-2	Photodegradation in water/soil
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
162-3	Anaerobic Aquatic Metabolism
162-4	Aerobic Aquatic
163-1	Leaching and Adsorption/Desorption
164-1	Soil Dissipation
164-2	Aquatic (Sediment)
164-5	Soil, Long Term
165-3	Irrigated crops
165-5	Accumulation Studies in Fish

§158.145 Wildlife and Aquatic Organisms

71-2	Avian Dietary LC_{50}
72-6	Aquatic Organism Accumulation (Fish)
70-1	Special Studies Field Monitoring

§158.150 Plant Protection

122-1	Seed Germination/Seedling Emergence
122-1	Vegetative vigor

B. Preliminary Risk Assessment

1. Acute Toxicology

There are no valid studies available to assess the potential acute oral and acute dermal toxicity of tebuthiuron. Studies are required. Sufficient data are available to assess the acute inhalation toxicity of technical tebuthiuron. The 4-hour LC_{50} in rats is greater than 3.696 mg/L. (Toxicity Category III).

There are no valid studies available to assess the primary dermal, and dermal sensitization potential of technical tebuthiuron; studies are required.

2. Chronic Toxicity

In a study of beagle dogs, 4 animals per sex per dose level were given technical tebuthiuron by capsule for one year at levels of 0 (Control), 12.5, 25.0, or 50.0 milligram per kilogram of body weight. The effects produced included increased liver to body weight ratios in high dose males and females; increased kidney to body weight ratios in high dose females, and increased thyroid ratios in high dose males. There were no adverse histopathological findings for these organs, however, alanine transaminase and alkaline phosphatase values were significantly increased in the high dose males, as was alanine transaminase in the high dose females. This indicates a significant hepatotoxic effect at this level in both sexes. Increased thrombocyte counts in the high dose males throughout the study appear to be an isolated finding. The NOEL based on these effects is 25 mg/kg bwt/day.

3. Oncogenicity

No acceptable oncogenicity studies are available. Studies in two species are required.

Tebuthiuron is one of a class of substituted dimethylurea compounds. Other such compounds include monuron and diuron. Monuron has produced increased incidences of renal tubular adenomas and carcinomas in male rats; diuron has produced increased incidences of bladder carcinomas in male and female mice. Linuron, a substituted monomethylurea compound, has induced testicular adenomas and interstitial cell tumors in male mice. These findings strongly suggest that urogenital tissues are sensitive to subtituted methylurea materials. However, further evaluation of tebuthiuron is not possible until the required oncogenicity studies are available.

4. Mutagenicity

An Ames assay was performed using bacterial strains of *S. Typhimurium* LT-2 with and without activation. Doses of technical tebuthiuron used were 5 to 5000 ug/plate. No tests showed evidence of induction of point mutation in 8 testor strains of *S. Typhimurium*. Technical tebuthiuron was not mutagenic either with or without metabolic activation.

Mouse lymphoma assay for the induction of forward mutations using the Tk+/- cell line was sensitive to direct acting and activation-dependant mutagens. Technical tebuthiuron was slightly mutagenic without metabolic activation. Mutation indices of 2.0, 2.0 and 2.7 were detected in technical tebuthiuron treated cultures at concentrations of 200, 400, and 500 ug/ml respectively. Technical tebuthiuron was not mutagenic in activated assays.

5. Teratology

A teratology study was submitted but was found to be inadequate to support registration of tebuthiuron. Gravid Harlan rats, 25 per group, were offered diets containing 0 (Control), 600, 1200, or 1800 ppm technical tebuthiuron on days 6 to 15 of gestation. No detailed analytical data, such as individual dam body weights or individual litter data were supplied. In adddition, the test material was offered in the diet rather than being given by gavage as recommended. Teratology studies in two mammalian species are required.

6. Reproduction

Sufficient data are available to satisfy the requirement for a multigeneration reproduction study. Harlan rats, 25/sex/dose, were offered diets containing 0 (Control), 100, 200, or 400 ppm 0(Control), 5, 10, or 20 mg/kg bwt/day) technical tebuthiuron through 2 generations of offspring. No adverse effects were reported except that F1 females, in the pre-mating phase, showed a lower rate of body weight gain in the 200 and 400 ppm groups. No adverse effects were reported on reproductive performance at any level. The NOEL for reproductive effects is > 400ppm (20 mg/kg bwt/day). The NOEL for systemic effects is 100 ppm (5.0 mg/kg bwt/day).

7. Subchronic Toxicity

Sufficent data are available to satisfy the requirment for subchronic dermal toxicity testing. New Zealand White rabbits, 10/sex/dose, were exposed dermally to 0 (control) or 1000 mg/kg of dry-form technical tebuthiuron applied to 10 percent of the total body surface area for 21 days, 6 hours per day. No signs of dermal toxicity or deaths were reported. Two of the ten treated animals showed slight erythema, which cleared by day 7. No systemic effects that could be attributed to dermal exposure were reported.

8. Metabolism

Radiolabeled technical tebuthiuron was administered in the diet at 100 and 200 ppm (5 and 10 mg/kg bwt/day, respectively), to lactating rats immediately postpartum. The period of diet administration was 48 hours. The dams were milked and the amount of activity in the milk was determined. The mean ^{14}C levels in rats' milk were 2.7 ppm and 6.2 ppm for the 100 and 200 ppm rats, respectively. Technical tebuthiuron and/or its metabolites appear in milk of lactating rats. General metabolism studies are not available for technical tebuthiuron. These studies are required.

C. Other Science Findings

1. Enviornmental Characteristics

Degradation

Tebuthiuron did not undergo significant degradation at pH 5, 7 and 9 at 25°C in 64 days and is considered stable in sterile water.

Preliminary data indicate that tebuthiuron is also quite stable under aerobic and anaerobic soil conditions. Tebuthiuron only degraded from 8 ppm to 5.7 ppm after 273 days (half life > 1 year) when incubated in loam soil at 25°C and was reported to degrade in an identical soil under anaerobic conditions with a halflife of >48 weeks. Similarly, irradiation with an artifical light that did not quite simulate sunlight resulted in only 42% decomposition after 15 days.

Tebuthiuron appears stable to biological and chemical degradation under environmental conditions and can be considered persistent.

Leaching

Preliminary data indicate that tebuthiuron is mobile to very mobile in loam, loamy sand, and lakeland sand soils and slightly mobile in silty loam soil. Values of lower than 2 were reported for clay, sandy loam and sand soils. About 40% of residues of a 30 days sandy loam aged tebuthiuron were found in the leachate.

Based on the above information, tebuthiuron has the potential to leach through a variety of soils and contaminate groundwater. Tebuthiuron was flagged as a groundwater contaminant through the GWDCI (Ground Water Data Call In) screen and has been found in shallow groundwater in Texas.

Tebuthiuron will be furthur analyzed in the Agency's National Pesticides in Well Water Survey.

Existing data which were submitted in response to a Ground Water Data Call-In have been found to be inadequate to fullfill Agency guideline requirements. Therefore, additional data are necessary to fully characterize tebuthiuron's ability to contaminate ground water.

2. Ecological Characteristics

Through dietary administration, tebuthiuron is no more than slightly toxic to birds; however, avian dietary data are incomplete. Avian reproductive studies show that tebuthiuron has no effect on avian reproduction at dietary levels up to 100 ppm.

Tebuthiuron is practically non-toxic (acutely) to fish and aquatic invertebrates. A fish early life-stage study gives a MATC (Maximum Allowable Toxic Concentration) between 9.3 and 18 mg/1 based on impaired growth. Aquatic invertebrates show significant reduction of growth and fecundity at 44 mg/1. The MATC for aquatic invertebrates is between 21.8 and 44.2 ppm.

Tebuthiuron was practially non-toxic to oyster embryos and slightly toxic to pink shrimp. No data are included on non-target insects. As some of the uses of tebuthiuron involve foliar application to non-crop areas, honey bee exposure is possible and toxicity to honey bees must be assessed. Therefore, a honeybee acute contact LD_{50} is required.

3. Residue Monitoring

In 1972 tebuthiuron was conditionally registered for control of brush in rangeland in Texas and Oklahoma. As a requirement of the registration the registrant was requested to perform a field monitoring study which would better define this chemical's actions in aquatic and terrestrial environments. Instead of a single monitoring study, several studies (EPA Accession No. 246373) were submitted by the registrant to fulfill the conditional requirement. While each study had several deficiencies and none of them would satisfy individually the data requirement, the series of studies were considered sufficient to satisfy the monitoring condition of the 1979 registration. In 1982, in response to a request for the addition of 17 states to the tebuthiuron registration, the Agency requested that the registrant continue (into a second year) the monitoring of water and hydrosoil at four study sites. The Agency is now requiring that these data be submitted to support the registration of tebuthiuron.

Because of tebuthiuron's extreme persistence, these monitoring data are still necessary to determine the long-term availability of the chemical for runoff into aquatic systems and the likelihood of long-term buildup of tebuthiuron in the soil. Monitoring data are being required through this Registration Standard. If information from past monitoring is not available or is determined to be unsatisfactory, a new monitoring study will be required.

4. Endangered Species

The use of tebuthiuron on rangeland, pastureland, and general noncrop areas should not pose a hazard to endangered or threatened terrestrial or aquatic animal species. However, the use of tebuthiuron on rangeland and pastureland will pose a hazard to endangered and threatened plant species. Products containing tebuthiuron with range and pasture uses which are released for shipment after February 1, 1988 must bear Endangered Species Labeling.

Endangered Species Labeling for non-crop, wide area, and general indoor/outdoor treatments is deferred until completion of the analysis by OES and the Agency of the Non-crop use Cluster.

5. Product Chemistry

The Agency has evaluated the available data, which identify the ingredients, materials, and manufacturing process and discuss the physical and chemical properties of tebuthiuron. In particular, the Agency has noted the possibility of the formation of nitrosamines. Analysis to identify and quantify nitrosamines is being required along with additional product chemistry data requirements identified in the data tables.

D. Tolerance Reassessment

Tolerances have been established for residues of tebuthiuron in a variety of raw agricultural commodities, in meat, fat, and meat byproducts (40 CFR 180.390). EPA has evaluated the residue and toxicology data supporting tolerances and has determined:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA section 24(c) and intrastate uses).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in Section IV.A, Regulatory Positions and Rationales.

1. Residue Data

The residue data reviewed in support of tebuthiuron tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of tebuthiuron. The metabolism is not completely understood. The available plant metabolism data from the sugarcane study are not adequate because 76 percent of the total ^{14}C-activity was nonextractable and was not characterized. The metabolites 104(OH), 106, 107, and 108 are not reported to be quantified by the residue analytical method for grasses.

b. Radiolabeled studies on the uptake, translocation, and metabolism of tebuthiuron in grass. These studies do not provide sufficient information regarding residues in plants.

c. Radiolabeled studies on the metabolism of tebuthiuron in ruminants, including milk. The ruminant studies are not adequate to permit conclusions regarding the adequacy of existing or pending tolerances. Animals must be dosed for at least 3 days with ringlabeled [14C] tebuthiuron at a concentration that will result in sufficient residues for characterization in the tissues and milk. This study must also elucidate the identities and quantities of all metabolities in milk, liver, kidney, muscle, and fat.

d. Storage stability data are needed which demonstrating residues of tebuthiuron are stable in or on plant and animal commodities. Sample history information is also needed.

e. Data on the magnitude and levels of residues of tebuthiuron in individual raw agricultural commodities, animal products, and processed food and feed items are needed.

2. Toxicology Data

The toxicology data considered in support of the tolerances include a 1-year dog feeding study,90-day rat feeding study and a multigeneration rat reproduction study. The one year dog study showed a NOEL of 25.0 mg/kg bwt/day based on increased liver, kidney, and thyroid gland ratios and increased alkaline phosphatase, alanine transaminase, and thrombocyte count values in high-dose males and females. The 90-day rat feeding study, had a NOEL of 50 mg/kg bwt/day based on increased liver and kidney in body weight ratio in males and females in the high-dose group.

3. Tolerances Issued

Tolerance are established for residues of the herbicide tebuthiuron and its metabolites containing the dimethyl ethyl thiadiazole moiety in or on the following raw agricultural commodities (40 CFR 180.390):

Commodities	Tolerance(ppm)
Cattle, fat	2
Cattle,*mbyp	2
Cattle, meat	2
Goat, fat	2
Goat, mbyp	2
Goat, meat	2
Grass, hay	20
Grass,rangeland,forage	20
Horse,fat	2
Horse,mbyp	2
Horse,meat	2
Milk	0.3
Sheep, fat	2
Sheep, mbyp	2
Sheep, meat	2

---

* mbyp meat product

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

Based on a review and evaluation of all available data and other relevant information on the herbicide tebuthiuron, the Agency has reached the determinations listed below.

1. The Agency will not place tebuthiuron into special review at this time.

Rationale: Based on available data tebuthiuron does not exceed the risk criteria for adverse effects in 40 CFR 154.7. Tebuthiuron is not acutely toxic by inhalation in rats and is Category III. Subchronic feeding studies in rats and chronic feeding studies in dogs indicate only mild effects on the liver, kidneys, gonads, spleen, and prostate and thyroid glands.

2. The Agency will not require reentry protection data to be submitted or impose an interim reentry interval for tebuthiuron products at this time.

Rationale: Tebuthiuron does not meet the criteria in Section 158.140 reentry data submitted: acute toxicity appears to be low (toxicity Category III by the inhalation route), and the Agency has insufficient evidence of chronic effects and no evidence of poisoning incidents associated with its use. Little reentry exposure would be expected from pre-emergent and early postemergent use of tebuthiuron on non-crop and rangeland sites.

3. The Agency's data on tebuthiuron in meat and milk residues are not being assessed at the present time. New data defining the nature of the residue in animals are required.

Rationale: The Agency has determined a secondary residue of tebuthiuron in meat and milk occurs through the ingestion by livestock of treated grass hay, forage, and range land. However, data defining the nature of the residue in animals are unavailable. Therefore, the adequacies of available data on these residues in meat and milk cannot be assessed.

4. The Agency is requiring endangered species labeling on tebuthiuron End-Use-Products registered for use on range and/or pastureland in accordance with PR Notice 87-5 (issued May 1, 1987).

Rationale: Tebuthiuron was reviewed for endangered species implications in consultation with the Office of Endangered Species, U.S. Fish and Wildlife Service. This review resulted in a determination that use of tebuthiuron on range and/or pastureland may pose jeopardy to endangered and threatened plant species. In order to protect these species from harm endangered species labeling is required. The Labeling is indentified in Section 4.D of this document.

5. The Agency will not require groundwater advisory statements on tebuthiuron products at this time, but will further evaluate the potential of tebuthiuron to contaminate ground water after it has received and evaluated additional required environmental fate data.

Rationale: Base on column leaching studies, tebuthiuron is mobile to very mobile in loam, sandy loam, and sand soils, which indicates that a potential for leaching into ground water exists. This potential, however, can not be fully characterized until the Leaching and Adsorption/Desorption studies are submitted.

6. Additional residue monitoring data for water and hydrosoil are required.

Rationale: Because of the extreme persistence of tebuthiuron, monitoring is essential in order to better determine the long-term availability of tebuthiuron for runoff into aquatic systems and the likelihood of long-term buildup of tebuthiuron in the hydrosoil.

7. The present precautionary statements for persons who handle tebuthiuron products are sufficient for the labels of manufacturing-use and end-use products.

Rationale: Available data indicate that tebuthiuron appears to have low acute toxicity (Category III). Therefore, the labeling of these products which contains statements that caution persons applying or handling this compound, give first aid instructions, and require the use of precautionary measures to ensure safe handling of pesticide product, are adequate.

8. The Agency is requiring residue data for rangeland, forage grasses, and grass hay.

Rationale: The data available are inadequate to support the group tolerance in animal feedstuffs because the studies submitted were for unidentified grass and forage.

9. The Agency has determined that, based on the available data, it will not establish further food tolerances pending receipt of the required chronic and oncogenicity studies.

Rationale: These studies must specifically address the question of potential oncogenic response in the urogenital system and the liver, with careful attention given to the histopathology of the kidney and other surrounding organs due to tebuthiuron's similarity to Linuron, Diuron and Monuron.

10. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency.

§158.130 Environmental Fate

161-2	Photodegradation in Water
161-3	Photodegradation on Soil
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
162-3	Anaerobic Aquatic Metabolism
162-4	Aerobic Aquatic Metabolism
163-1	Leaching and Adsorption/Desorption
164-1	Soil Dissipation
164-2	Aquatic (sediment) Dissipation
164-5	Soil, Long Term Dissipation

§158.145 Wildlife and Aquatic Organisms

70-1 Special Studies - Field Monitoring

§158.150 Plant Protection

122-1 Tier I - Seed Germination/Seedling Emergence
122-1 Tier I - Vegetative Vigor

11. While data gaps are being filled, currently registered manufacturing-use products and end-use products containing tebuthiuron must be formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data as specified in the data appendices in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or are inadequate. See FIFRA section 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain Tebuthiuron as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain Tebuthiuron as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing Tebuthiuron provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products registered for the uses listed in Appendix B, EPA Index to Pesticide Chemicals -- Tebuthiuron. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

Products subject to the requirements of this Registratiion Standard may not be released for shipment after August 1, 1988 unless the product bears amended labeling which complies with the requirements of this Standard. [EXCEPTION: Endangered Species labeling must be on products released for shipment after February 1, 1988 and on all products after February 1, 1989 as specified in Pesticide Registration (PR) Notice 87-5 (issued May 1, 1987).] After reviewing data to be submitted under this Standard, the Agency may impose additional labeling requirements.

Products subject to the requirements of this Registration Standard may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after August 1, 1989 unless the product bears amended labeling which complies with the requirements of this standard.

All products must bear appropriate labeling as specified in 40 CFR 162.10 and in Pesticide Registration Notices applicable to these products. Specific information regarding 40 CFR 162.10 label requirements is included in Appendix II.

Ingredients Statement

The ingredient statement for MPs must list the active ingredient as:

N-[5-1,1-dimethylethyl 1-1,3,4-thiadiazol-2yl]
N,N'dimethylurea

Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Appendix B, EPA Index to Pesticide Chemicals -- Tebuthiuron. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

Required Precautionary Labeling Statement

Manufacturing-Use Products

"Do not discharge effluent containing this product into lakes, stream, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in the NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewer treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

End-Use Products with Granular/Pelleted Use

"Collect, cover, or incorporate granules/pellets spilled on the soil surface. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

End-Use Products with Nongranular/Nonpelleted Use

"Do not apply directly to water or wetlands (swamps, bogs, marshes,and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes."

End-Use Products with Ditchbank Use

"Do not apply to any portion of the ditchbank that will come into contact with water. Do not apply on ditches used to transport irrigation or potable water."

End-Use Products with Range and/or Pastureland Use

The following information on endangered species must appear on the labeling of all EPs registered for use on range and/or pastureland. Statement "A" is to be used on product labels only if Statement "B" is not on the product label, but instead, in the product labeling.

[NOTE - EXCEPTIONS: Products used directly on humans or pets; in, on or around any structure, or vehicle, article, surface, or area associated with the household, including but not limited to areas such as out-buildings, non-commercial greenhouses, pleasure boats, and recreational vehicles, or in any pre-school or day care facility, and which are labeled only for such uses are exempt from the labeling requirements to protect endangered species.]

A. "Refer to product labeling for use restrictions to protect ENDANGERED SPECIES."

B. "ENDANGERED SPECIES RESTRICTIONS

The following restrictions apply to use of this product after February 1, 1988.

Before using this pesticide on range and/or pastureland in the counties listed below, you must obtain the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES for the county in which the product is to be used. The bulletin is available from your County Agricultural Extension Agenct, State Fish or Game Office, or your pesticide dealer. Use of this product in a manner inconsistent with the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES is a violation of Federal laws.

ALABAMA
Cherokee, DeKalb, Etowah, Jackson and Marshall

ARIZONA
Cochise, Coconino, Gila, Graham, Maricopa, Mohave, Navajo, Pima, Pinal, and Yavapai

CALIFORNIA
Alameda, Butte, Colusa, Contra Costa, Fresno, Glann, Inyo, Lake, Los Angeles, Mendocino, Merced, Nevada, Orange, Sacramento, San Benito, San Bernardino, San Clemente Island, San Diego, San Francisco, San Joaquin, San Luis Obispo, San Mateo, Santa Barbara, Santa Barbara Island, Solano, Sutter, Tehema, Ventura and Yolo

COLORADO
Delta, Jackson, La Plata, Mesa, Montezuma and Montrose

FLORIDA
Charlotte, Franklin, Jefferson, Lee, Liberty and Orange

GEORGIA
Brantley, Towns and Wayne

HAWAII
Islands of Hawaii and Maui and the District of Lahaina

IDAHO
Idaho

ILLINOIS
DuPage, Lee, McHenry, Ogle and Winnebago

IOWA
Butler, Clarke, Dickinson, Emmet, Howard, Kossuth, Lucas, Oscocola, Story and Winneshiek

KENTUCKY
Fleming, Nicholas and Robertson

MINNESOTA
Cottonwood, Goodhue, Jackson and Renville

MISSOURI
Christian, Dade and Greene

NEBRASKA
Cherry, Garden and Hooker

NEVADA
Nye

NEW MEXICO
Catron, Chaves, Dona Ana, Eddy, Lincoln, McKinley, Otero, San Juan and Sierra

NORTH CAROLINA
Henderson

OREGON
Harney and Wallowa

SOUTH CAROLINA
Greenville and McCormick

TENNESSEE
Davidson, Rutherford and Wilson

TEXAS
Bandera, Brazos, Brewster, Burleson, Culberson, Edwards, El Paso, Grimes, Harris, Hays, Hudspeth, Jim Wells, Kerr, Kimble, Kleburg, Nueces, Pecos, Presidio, Real, Refugio, Robertson, Runnels, San Augustine, Starr, Terrell, Uvalde, Val Verde and Zapata

UTAH
Beaver, Cache, Carbon, Duchesne, Emery, Garfield, Grand, iron, Kane, Piute, San Juan, Sanpete, Sevier, Uintah, Utah, Washington and Wayne

WISCONSIN
Dane, Pierce, Rock and Sauk "

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2].
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

---

[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If not eligible for the formulator's exemption, the data requirements listed in Table A.

3. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the data requirements listed in Table A.

---

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

---

[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

VIII. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

---

[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

b. Five copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Addresses

The required information must be submitted to the following address:

Robert J. Taylor (PM 25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.120 Product Chemistry					
Product Identity					
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	desk reference	No 1/	
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00020664, 00020742, 00020706, 00020743, 00148606	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	Partially	00020706, 00148606	Yes 3/	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	Partially	00156561, 00020744, 00156562, 00027811	Yes 4/	12 Months
62-2 - Certification of Ingredients	TGAI	No		Yes 5/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	00020728, 00156562, 00156561, 00020744, 00027811	Yes 6/	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No		Yes 7/	6 Months
63-3 - Physical State	TGAI	No		Yes 7/	6 Months
63-4 - Odor	TGAI	No		Yes 7/	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Does EPA Have Data to satisfy This Requirement? (Yes, No, Or Partially	bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Submission
§158.120 Product Chemistry (cont'd)					
Physical and Chemical Characteristics (cont'd)					
63-5 - Melting Point	TGAI	No		Yes 7/	6 Months
63- Boiling Point	TGAI	No		Yes 7/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes 7/	6 Months
63-8 - Solubility	TGAI or PAI	Yes	00020773	No	
63-9 - Vapor Pressure	PAI	Yes	00020773	No	
63-10 - Dissociation Constant	PAI	No		Yes 7/	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	Yes	00020781	No	
63-12 - pH	TGAI	No		Yes 7/	6 Months
63-13 - Storage Stability	TGAI	No		Yes 7/	15 Months
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A		No 8/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Does EPA Have Data to satisfy This Requirement? (Yes, No, Or Partially	bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Submission
§158.120 Product Chemistry (cont'd)					
Physical and Chemical Characteristics (cont'd)					
63-5 - Melting Point	TGAI	No		Yes 7/	6 Months
63- Boiling Point	TGAI	No		Yes 7/	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes 7/	6 Months
63-8 - Solubility	TGAI or PAI	Yes	00020773	No	
63-9 - Vapor Pressure	PAI	Yes	00020773	No	
63-10 - Dissociation Constant	PAI	No		Yes 7/	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	Yes	00020781	No	
63-12 - pH	TGAI	No		Yes 7/	6 Months
63-13 - Storage Stability	TGAI	No		Yes 7/	15 Months
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A		No 8/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

---

§158.120 Product Chemistry Footnotes

1/ Information obtained from desk reference.

2/ The name and address of the manufacturer, supplier, or producer of each beginning material must be provided, along with information regarding the properties of each beginning material.

3/ A detailed discussion of all impurities that are or may be present at > 0.1%, based on knowledge of the beginning materials (including impurities), chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.

4/ Complete validation data (accuracy, precision) must be submitted for each method used. In addition, all nitrosamines must be identified and quantified in six samples; two samples must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used.

5/ Upper and lower limits for tebuthiuron must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for each impurity present at ≥ 0.1% (w/w) and for each toxicologically significant impurity present at < 0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Upper limits for all nitrosamines must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Certifications must be submitted on EPA Form 8570 (Rev. 2-85).

6/ Analytical methods must be submitted to determine each toxicologically significant impurity for which a certified limit is required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

7/ All physical/chemical characteristics (color, physical state, odor, melting point, specific gravity, Kow, pH, and stability) for the 95% T, as required in 49 FR 42890 (Section 158.120) and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

8/ Data are not required to support currently registered uses or are otherwise not applicable for this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement §158.125 Residue Chemistry	Test Substance	Does EPA Have To Satisfy This Requirement? (Yes No, or Partially	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submisson
171-4 - Nature of the Residue (Metabolism)					
- Plants	PAIRA	Partially	00020645,00020756, 00020766	Yes 1/,2/	18 Months
- Livestock	PAIRA	Partially	00020648,00020650, 00020651,00020652, 00020721,00020767, 00027805,00027810, 00041675,00106080	Yes 3/,4/	18 Months
171-4 - Residue Analytical Methods					
- Plant and Animal Residues	PAI	Partially	00020656,00020740, 00041673,00094745, 00106080	Yes 5/,6/	15 Months
171-4 - Storage Stability Data	PAI	No		Yes 7/ 8/	15 Months
171-4 - Magnitude of the Residue					
- Grass Forage, Fodder, and Hay Group	TEP	Partially	00020705,00020757, 00020764,00041671, 00094745	Yes 9/,10/	18 Months
- Meat/Milk/Poultry/Eggs		Partially	00041673	Reserved 11/,12/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

§158.125 Residue Chemistry Footnotes

1/ Data must be depicting the uptake, distribution, and metabolism of thiadiazole ring-labeled [^{14}C] tebuthiuron in rangeland and conducted pasture grass following broadcast application at a rate sufficiently high to permit complete ^{14}C residue identification.

2/ Representative samples from the required metabolism studies must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all possible metabolites of concern.

3/ A metabolism study utilizing ruminants must be submitted. Animals must be dosed for at least 3 days with ring-labeled [14C] tebuthiuron at a concentration that will result in sufficient residues for characterization in the tissues and milk. Studies must also elucidate the identities and quantities of all metabolites in milk, liver, kidney, muscle, and fat. Milk must be collected twice daily during the dosing period. Animal must be sacrificed within 24 hours of the final dose. Since grass is not a poultry feed item, no poultry metabolism study is required at this time.

4/ Representative samples from the above described test must also be analyzed by current enforcement methods to ascertain the validity of these methods.

5/ Residues of tebuthiuron and metabolites 104, 106, 109, and 103(OH) in or on crop samples must be subjected to analysis by multiresidue protocols. Protocols for Methods I, II, III, and IV are available from the National Technical Information Service under Order No. PB 203734/AS.

6/ Additional methods, validation data, and residue data (for representative commodities) may be required if the metabolism studies requested in the sections entitled "Nature of the Residue in Plants" and "Nature of the Residue in Animals" reveal additional metabolites of toxicological concern in or on plants or in animals.

7/ The storage intervals and conditions must be submitted for all samples used to support all tolerances for residues of tebuthiuron in or on plant and animal commodities. These data must be accompanied by data depicting the decline of residues during the intervals and under the conditions specified.

8/ Residue data requested in this Standard must be accompanied by information describing the storage conditions and intervals for all samples analyzed. These data must be accompanied by fortification recovery data depicting the stability of residues of concern in appropriate sample substrates under the storage conditions and for the time intervals specified.

9/ Data must be submitted depicting tebuthiuron residues of concern in or on fresh grass and field-dried hay of bermudagrass, bluegrass, and bromegrass or fescue treated with a single application of a Pellet/Tablets formulation, by ground or air equipment, at 4 lb/ai/A. Fresh grass samples must be collected every 2 weeks for the first 3 months following application, and monthly for the following 21 months in order to determine the maximum residue level that may occur any time following application. Hay samples must be collected up to 2 years following the application. If other grasses are tested, the grass species must be identified for each test and the species must be representative for the region in which it was tested. Tests must be conducted in AR (3%), KS (4%), KY (6%), MO (11%), NY (5%), OK (4%), PA (4%), TN (4%), TX (13%), and VA (3%), which collectively produced ca. 57% of the total domestic hay crop in 1982 (production figures follow in parentheses). Tests must also be conducted in CO (3%), NE (16%), ND (10%), OR (4%), SD (12%), TX (2%), and WY (5%), which together with KS (8%) and OK (5%), collectively produced ca. 65% of the total wild hay crop (and thus represent rangeland grasses) in 1982. The

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

§158-125 Residue Chemistry Footnote (cont'd)

combined tests will adequately represent the major rangeland and pasture regions of the U.S.

10/ Data depicting tebuthiuron residues of concern in or on fresh grass grown around roots of brush and vine clumps treated with a Pellet/tablet formulation at 5.9 lb/ai/A. Grass species must be representative of the region in which the species is grown. Tests must be conducted in major rangeland regions of the United States.

11/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the appropriate nature of tolerances for residues in animal products will be determined and, with consideration for any newly found metabolites of toxicological concern, the adequacy of the available data regarding the magnitude of the residue in fat, meat, and meat byproducts will be determined.

12/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue in Animals," the need for and nature of data regarding the magnitude of residues in milk will be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have To Satisfy This Requirement? Yes, No, or Partially	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate						
Degradation Studies-Lab						
161-1 - Hydrolysis	PAIRA	B,D	Yes	00020779	No	
Photodegradation						
161-2 - In Water	PAIRA	B,D	No		Yes	9 Months
161-3 - On Soil	PAIRA	B,D	No		Yes	9 Months
161-4 - In Air	PAIRA	B,D	No		No 1/	
Metabolism Studies-Lab						
162-1 - Aerobic Soil	PAIRA	B	No		Yes	27 Months
162-2 - Anaerobic Soil	PAIRA	B	No		Yes 2/	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes	27 Months
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	PAIRA	B,D	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	---	No		No 1/	
163-3 - Volatility (Field)	TEP	---	No		No 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have To Satisfy This Requirement? (Yes No, or Partially	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.130 Environmental Fate (cont'd)						
Dissipation Studies-Field						
164-1 - Soil	TEP	B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes	27 Months
164-3 - Forestry	TEP	--	No		No1/	
164-4 - Combination and Tank Mixes						
164-5 - Soil, Long-Term	TEP	B	No		Yes 3/	50 Months
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	B	No		No4/	
165-2 - Rotational Crops (Field)	TEP	B	No		No4/	
165-3 - Irrigated Crops	TEP	D	No		Yes	39 Months
165-4 - In Fish	PAIRA	B,D	No.		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	--	No		No5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

---

§158.130 Environmental Fate Footnote

1/ Data are not required to support current registered uses or are otherwise not applicable for this Standard
2/ Anaerobic soil metabolism data are required since available leaching data indicate that tebuthiuron has the potential to leach to depths where anaerobic conditions exist.
3/ Required pending results of field dissipation study.
4/ Not required as long as the land to which tebuthiuron is applied is not intended for future crop use.
5/ Unless requested by EEB.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.135 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TGAI	A,B,D	No		Yes	9 Months
81-2 - Acute Dermal	TGAI	A,B,D	No		Yes	9 Months
81-3 - Acute Inhalation - Rat	TGAI	A,B,D	Yes	00155730	No	
81-4 - Eye Irritation - Rabbit	TGAI	A,B,D	No		Yes	9 Months
81-5 - Dermal Irritation - Rabbit	TGAI	A,B,D	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B,D	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,D	No		No 1/	
Subchronic Testing						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A,B,D	Yes	00020662	No	
- Nonrodent	TGAI	A,B,D	No		No 2/	
82-2 - 21-Day Dermal	TGAI	A,B,D	Yes	00149733	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.135 Toxicology						
Subchronic Testing (cont'd)						
82-3 - 90-Day Dermal	TGAI	A,B,D	No		No 3/	
82-4 - 90-Day Inhalation	TGAI	A,B,D	No		No 3/	
82-5 - 90-Day Neurotoxicity	TGAI	A,B,D	No		No 4/	
Chronic Testing:						
83-1 - Chronic Toxicity						
- Rodent	TGAI	A,B,D	No		Yes	50 Months
- Nonrodent	TGAI	A,B,D	Yes	00146801	No	
83-2 - Oncogenicity Study						
- Rat	TGAI	A,B,D	No		Yes	50 Months
- Mouse	TGAI	A,B,D	No		Yes	50 Months
83-3 - Teratogenicity						
- Rat	TGAI	A,B,D	No		Yes	15 Months
- Rabbit	TGAI	A,B,D	No		Yes	15 Months
83-4 - Reproduction	TGAI	A,B,D	Yes	00020739, 00090108	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.135 Toxicology (cont'd)						
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A,B,D	Yes	00144041, 00141691	No	
84-2 - Chromosomal Aberration	TGAI	A,B,D	No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,D	No		Yes	12 Months
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A,B,D	Partially	00106081	Yes 5/	24 Months

---

1/ This is only for compounds that are organophosphate inhibitors of chlinesterase, or related to such inhibitors or are metabolites of such inhibitors. Tebuthiuron is not an organophosphate; therefore, a study is not required.

2/ A subchronic oral toxicity study in a nonrodent species is not required because there is a 1-year dog study avalable.

3/ This study is not required for the present use pattern.

4/ Since an acute neurotoxicity study is not required, and there is no evidence of neurotoxicity in mammalian species, this study is not required.

5/ Data defining the absorption, distribution, and metabolites and their excretion patterns must be submitted and are required.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Oral LD_{50}	TGAI	B	Yes	00041692	No	
71-2 - Avian Dietary LC_{50}	TGAI	B	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	B	No		No 1/	
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	B	Yes	00104243	No	
- Waterfowl	TGAI	B	Yes	00093690	No	
71-5 - Simulated and Actual Field Testing						
- Mammals and Birds	TEP	B	No		No 1/	
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	B	Yes	00020661	No	
- Coldwater	TGAI	B	Yes	00020661	No	
72-2 - Acute LC_{50} Freshwater Invertebrate	TGAI	B	Yes	00041694	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms (cont'd)						
Aquatic Organism Testing (cont'd)						
72-3 - Acute LC_{50} Estuarine and Marine Organisms						
- Fish	TGAI	B	No		No 2/	
- Shrimp	TGAI	B	Yes	00041684	No	
- Oyster	TGAI	B	Yes	00041684	No	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
Fish						
- Fathead Minnow	TGAI	B	Yes 3/	00090084	No	
- Rainbow Trout	TGAI	B	Yes 3/	00090083	No	
Invertebrate						
- *Daphnia magna*	TGAI	B	Yes 3/	00138700	No	
72-5 - Fish Life Cycle						
- Estuarine	TGAI	B	No		No 1/	
- Freshwater	TGAI	B	No		No 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
Organisms (cont'd)						
Aquatic Organism Testing (cont'd)						
72-6 - Aquatic Organism Accumulation (Fish)	TGAI	B	No		Yes 4/	12 Months
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TGAI	B	No		No 1/	
70-1 - Special Studies Field Monitoring	TEP	B	Partially	00090105, 00090106, 00090107, 00090109	Yes 5/	36 Months

---

1/ Available information on this chemical and its use pattern indicate the study is not required.

2/ The requirement for testing with a marine or estuarine fish species will be waived because of the demonstrated low toxicity of tebuthiuron to fresh water fish.

3/ Tebuthiuron is expected to transport to water with terrestrial use. Tebuthiuron is persistent in water (half-life greater than 4 days).

4/ Required by the Exposure Assessment Branch, OPP, EPA.

5/ Needed are additional residue monitoring data for water and hydrosoil. In 1982, the registrant was requested to continue (into the second year) the monitoring of water and hydrosoil at the four study sites, especially in the catchment pond at the Marietta, Oklahoma site. Tebuthiuron is extremely persistent in soil (half-life 11 to 61 months). Because of this persistence, this additional monitoring is essential in order to better determine the long term availability of tebuthiuron for runoff into aquatic systems and the likelihood of long -term buildup of tebuthiuron in the hydrosoil. Monitoring should be conducted at least into the second year. If additional monitoring was not conducted at that time and if no data addressing the above concerns are available, the registrant is required to submit a protocol for additional monitoring within 6 months. This residue moniotoring (for a rangeland use) should be a multiple year study and should be conducted at four separate sites representing a wide range of climatic, edaphic, and geographical conditions. A pelleted/tableted formulation should be used.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.150 Plant Protection						
121.1 - Target Area Phytotoxicity	TEP	B	No		No 1/	
Nontarget Area Phytoxicity						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		Yes 2/	9 Months
122-1 - Vegetative Vigor	TGAI	B	No		Yes 2/	9 Months
122-2 - Aquatic Plant Growth	TGAI	B	Yes	00138697	No	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		Reserved 3/	
123-1 - Vegetative Vigor	TGAI	B	No		Reserved 3/	
123-2 - Aquatic Plant Growth	TGAI	B	No		Reserved 3/	
TIER III						
124-1 - Terrestrial Field	TEP	B	No		Reserved 4/	
124-2 - Aquatic Field	TEP	B	No		Reserved 4/	

§158.150 Plant Protection Footnotes

1/ Data are required only on a case to case basis.
2/ In the opinion provided by the Office of Endangered Species for the Rangeland Cluster, tebuthiuron was listed as causing jeopardy to endangered and threatened plant species.
3/ Reserved pending results of Tier I phytotoxicity tests.
4/ Reserved pending results of Tier II phytotoxicity tests.

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.155 Nontarget Insect Testing						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	B	No		Yes	9 Months
141-2 - Honey Bee - Toxicity of Residues of Foliage	TEP	B	No		Reserved 1/	
141-4 - Honey Bee Subacute Feeding Study	Reserved 2/					
141-5 - Field Testing for Pollinators	TEP	B	No		Reserved 2/	
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects	Reserved 3/					
142-1 - Aquatic Insect Life Cycle Study	Reserved 3/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved 3/					
143-1 thru 143-3 - Nontarget Insect Testing - Predators and Parasites	Reserved 3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR TEBUTHIURON

§158.155 Nontarget Insect Testing Footnotes

1/ Requirement deferred pending receipt of data from honey bee acute contact LD_{50} test.
2/ Reserved pending development of test methodology.
3/ Reserved pending Agency decision as to whether the data requirement should be established.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tebuthiuron Standard

MRID	CITATION
00020645	Rainey, D.P.; Magnussen, J.D. (1975) Metabolism of 14C EL-103 in Sugarcane. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-E)
00020648	Rainey, D.P.; Magnussen, J.D.; Herberg, R.J. (1975) 14C EL-103 in the Ruminant Excretion and Tissue Residues. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 094913-H)
00020650	Herberg, R.J. (1975) 14C EL-103 Milk Residue Experiment: Experiment VPR 330-766. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-J)
00020651	Herberg, R.J. (1975) 14C EL-103 Swine Tissue Residue Study: Experiment SW-457. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-K)
00020652	Herberg, R.J. (1975) 14C EL-103 Chicken Tissue Residue Study: Experiment VPR 335-766B. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-L)
00020656	Decker, O.D.; Sullivan, W.L.; Sherman, W.E. (1975) Determination of Tebuthiuron and Metabolites in Cattle Tissues. Undated method 5801644. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-Q)
00020661	Todd, G.C.; Kehr, C.C.; West, H.C.; et al. (1972) The Acute Toxicity of EL-103 in Mice, Rats, Rabbits, Cats, Dogs, Quail, Ducks, Chickens, and Fish. (Unpublished study received Mar 13, 1973 under 1471-97; prepared in cooperation with Bionomics, Inc., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006422-F)
00020662	Todd, G.C.; Gibson, W.R.; Kiplinger, G.F. (1972) The Toxicological Evaluation of EL-103 in Rats for 3 Months. (Unpublished study received Mar 13, 1973 under 1471-97; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 006422-G)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Tebuthiuron Standard

MRID	CITATION
00020664	Elanco Products Company (19??) Preparation of Spike 80W (EL 103). (Unpublished study received Apr 20, 1977 under 1471-97; CDL: 229361-C)
00020705	Loh, A. (1978) Residue Data on Tebuthiuron and Metabolites in Forage Grass and Hay. (Unpublished study received Apr 6, 1978 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:097019-B)
00020706	Tao, E.V.P. (1977) Appraisal of Thioureas in Tebuthiuron. (Unpublished study received Apr 6, 1978 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:097019-C)
00020714	Todd, G.C.; Gibson, W.R.; Hoffman, D.G.; et al. (1976) The Toxicological Evaluation of Tebuthiuron (EL-103) in Rats for Two Years: Toxicology Report # 7. (Unpublished study received Dec 1, 1976 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:230139-A)
00020717	Todd, G.C.; Gibson, W.R.; Hoffman, D.G.; et al. (1976) The Toxicological Evaluation of Tebuthiuron (EL-103) in Mice for Two Years: Toxicology Report # 8. (Unpublished study received Dec 1, 1976 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:230139-D)
00020721	Rainey, D.P. (1976) Characterization of Milk Residues from a Cow Fed 14C-Tebuthiuron. (Unpublished study received Dec 23, 1976 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:237161-B)
00020728	Eli Lilly and Company (1973) Raw Material: Corporate Control Laboratory Procedure. Method OA 182R dated Oct 23, 1973. (Unpublished study.
00020739	Adams, E.R.; Todd, G.C. (1979) Additional Statistical Analyses and Discussion of Body Weight Data in the Multi-Generation Reproduction Study with EL-103 in the Rat. (Unpublished study received May 22, 1979 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:098312-A)
00020740	Macy, T.D.; Loh, A. (1977) Determination of Tebuthiuron and Metabolites in Milk and Cattle Tissues. Undated method no. 5801684. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095848-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Tebuthiuron Standard

MRID	CITATION
00020742	Tao, E.V.P. (1977) Preparation of EL103. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 095848-G)
00020743	Tao, E.V.P. (1976) Source and Purity of Starting Materials for Spike. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095848-H)
00020744	Frank, R. (19??) Determination of Tebuthiuron and Its Related Manufacturing By-Products in Technical Grade Material. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095848-I)
00020750	Elanco Products Company (19??) Storage Stability. (Unpublished study received Feb 18, 1977 under 1471-109; CDL:095848-P)
00020756	Rainey, D.P.; Magnussen, J.D. (1976) Metabolism of 14C Tebuthiuron in Range Grasses: Supplemental Report. (Unpublished study received Sep 29, 1976 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 095298-C)
00020757	Loh, A.; Macy, T.D. (1976) Tebuthiuron and Metabolites in Forage Grass. (Unpublished study received Sep 29, 1976 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095298-D)
00020764	Bovey, R.W. (1975) Summary of Data. Summary of study 210135-E. (Unpublished study received Sep 3, 1975 under 1471-EX-43; prepared by Texas A & M Univ., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094906-F)
00020766	Rainey, D.; Magnussen, J. (1975) Metabolism of 14C Tebuthiuron in Range Grasses. Unpublished study.
00020767	Herberg, R.J. (1975) 14C EL-103 0.04 PPM Milk Residue Study: Experiment VPR 343-766. (Unpublished study received Sep 3, 1975 under 1471-EX-43; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094906-J)
00020773	Elanco Products Company (19??) Chemical and Physical Properties: EL-103. (Unpublished study received Aug 16, 1977 under unknown admin. no.; CDL:231275-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tebuthiuron Standard

MRID	CITATION
00020779	Mosier, J.W.; Saunders, D.G. (1976) A Hydrolysis Study on the Herbicide Tebuthiuron. Includes undated method. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095854-F)
00020781	Macy, T.D.; Loh, A. (1976) N-Octanol-to-Water Partition Coefficient of Tebuthiuron. Includes method dated Nov 1976. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095854-H)
00020803	Todd, G.C.; Markham, J.K.; Adams, E.R.; et al. (1972) Rat Teratology Study with EL-103. (Unpublished study received Mar 13, 1973 under 1471-97; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006422-O)
00027805	Herberg, R.J. (1975) 14C EL-103 Chicken Egg Residue Experiment: Experiment VPR 334-766. (Unpublished study received Jul 9, 1975 under 5G1562; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:094913-M)
00027811	Day, E.; Koenig, D. (1976) Determination of N-Nitroso Contaminants in Tebuthiuron Technical and Spike Pelleted Formulations. Includes undated method. Unpublished study.
00028710	Channon, E.J.; Cryer, P.C. (1978?) Amitraz: Investigation of Effects on the Thymus Gland and Oestrous Cycle in Mice--Statistical Analysis of Vaginal Smear Data and Thymus Weights: SS78001; C13. (Unpublished study received Apr 9, 1980 under 43142-EX-1; submitted by Boots Hercules Agrochemicals Co., Wilmington, Del.; CDL:099363-O)
00034756	Davis, E.A.; Sullivan, W.L.; Loh, A. (1980) Tebuthiuron Residues in Stream Water following the Spot Treatment of a Chaparral Watershed in Arizona. (Unpublished study received May 8, 1980 under 1471-109; prepared in cooperation with Arizona State Univ., Rocky Mountain Forest and Range Experiment Station, Forestry Sciences Laboratory, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:242458-A)
00041671	Frank, R.; Loh, A.; Macy, T. (1976) Residue Data on Tebuthiuron and Metabolites in Forage Grass. Includes undated method no. 5801667. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095852-D)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tebuthiuron Standard

MRID	CITATION
00041673	Day, E.W.; Decker, O.D. (1976) Residue Data on Tebuthiuron and Metabolites in Cattle Tissue. Includes undated methods ATW and 5801661. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095852-F)
00041675	Rainey, D.P.; Magnussen, J.D.; Herberg, R.J. (1976) Determination and Chacterization of Radioactive Residues in Milk from a Cow Given 14C Tebuthiuron. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095852-H)
00041684	Heitmuller, T.; Parrish, R. (1976) Acute Toxicity of EL-103 to Embryos of Eastern Oysters (Crassostrea virginica), to Pink Shrimp (Penaeus duorarum), and to Fiddler Crabs (Uca pugilator). (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095855-H)
00041692	Kehr, C.C.; Hamelink, J.L.; Todd, G.C.; et al. (1978) The Acute Oral Toxicity of Compound 75503 (EL-103) in Mallard Ducks: Study 7021-77. (Unpublished study received Jun 1, 1978 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:097102-A)
00041694	Hamelink, J.L.; Todd, G.C.; Brannon, D.R.; et al. (1978) Acute Toxicity of Compound 75503 (EL-103) to Daphnia magna: Study 5058-77. (Unpublished study received Jun 1, 1978 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:097102-C)
00090083	Sauter, S.; Meyerhoff, R.D.; Todd, G.C.; et al. (1981) The Toxicity of Tebuthiuron (EL-103, Compound 75503) in Water to Rainbow Trout (Salmo gairdneri) in a 45-day Embryo-larvae Study: Study F14580. Includes method AM-AA-CA-J024-AB-755 dated Jan 26, 1981. (Unpublished study received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246375-A)
00090084	Sauter, S.; Meyerhoff, R.D.; Todd, G.C.; et al. (1981) The Toxicity of Tebuthiuron (EL-103, Compound 75503) in Water to Fathead Minnows (Pimephales promelas) in a 33-day Embryo-larvae Study: Study F08381. Includes method AM-AA-CA-J024-AB-755 dated Jan 26, 1981. (Unpublished study received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246375-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Tebuthiuron Standard

MRID	CITATION
00090106	Loh, A.; Davis, E.A.; Helmer, J.D.; et al. (1981) Creation of Brush Grass Mosaics in Arizona Chaparral Watershed Study with Tebuthiuron. (Unpublished study, including published data, received Dec 10, 1981 under 1471-109; prepared in cooperation with Arizona State Univ., Rocky Mountain Forest and Range Experiment Station, Forest Sciences Laboratory, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246373-J)
00090107	Loh, A.; Bjerregaard, R.S.; Eaton, B.J. (1981) Evaluation of Graslan (Tebuthiuron) for Possible Contamination of Catchments following Application for Rangeland Brush Control: Experiment RSB81-2, Hondo, Texas. (Unpublished study, including published data, received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246373-K)
00090108	Hoyt, J.A.; Adams, E.R.; Owen, N.V.; et al. (1981) A Two-generation Reproduction Study with Tebuthiuron (Compound 75503) in the Wistar Rat: Studies R03780 and R08780. (Unpublished study received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246374-A)
00090109	Loh, A.; Bjerregaard, R.S.; Eaton, B.J. (1981) Evaluation of Graslan (Tebuthiuron) for Possible Contamination of Catchments following Application for Rangeland Brush Control: Experiment RSB81-1, Marietta, Oklahoma. (Unpublished study, including published data, received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246373-L)
00093690	Fink, R.; Beavers, J.B.; Brown, R. (1978) Final Report: One-generation Reproduction Study--Mallard Duck: Compound 75503, Tebuthiuron: Project No. 151-105. (Unpublished study received Jan 7, 1982 under 1471-109; prepared by Wildlife International, Ltd., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246557-B)
00094745	Elanco Products Company (1982) Summary Report of Tebuthiuron Residues in Forage Grass and Animal Tissues. Includes procedures 5801667 dated Nov 16, 1978 and 5801643 dated Apr 2, 1975. (Compilation; unpublished study received Feb 11, 1982 under 1471-109; CDL:246779-D)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Tebuthiuron Standard

MRID	CITATION
00104243	Fink, R.; Beavers, J.B.; Brown, R. (1978) Final Report: One-generation Reproduction Study--Bobwhite Quail: Compound 75503, Tebuthiuron: Project No. 151-104. (Unpublished study received Jan 7, 1982 under 1471-109; prepared by Wildlife International, Ltd., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246557-A)
00106080	Elanco Products Co. (1982) Residues of 14C Tebuthiuron in Milk. (Compilation; unpublished study received Jul 15, 1982 under 1471-109; CDL:070985-B)
00106081	Adams, E.; Magnussen, J.; Emmerson, J.; et al. (1982) Radiocarbon Levels in the Milk of Lactating Rats Given 14C Tebuthiuron (Compound 75503) in the Diet: Study R13781. (Unpublished study received Jul 15, 1982 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL: 070985-C)
00149733	Brown, G. (1985) Subchronic (21-Day) Dermal Toxicity Study in New Zealand White Rabbits with Technical Tebuthiuron: Study B01484. Unpublished study prepared by Lilly Research Laboratories. 211 p.
00155730	Markey, T. (1985) The Acute Inhalation Toxicity of Technical Tebuthiuron (EL-103, Compound 75503): Study No. R-H-023-85. Unpublished study prepared by Lilly Research Laboratories. 15 p.

EPA Index to Pesticide Chemicals

DRAFT
SAI / MAI
105501

TEBUTHIURON

TABLE OF CONTENTS

Site Name | Page

TERRESTRIAL NONFOOD CROP 9
(Agricultural Crops) 9
Brush 9
Pastureland 9
Rangeland 9
(Noncrop, Wide Area, and General Indoor/Outdoor Treatments) 11
Airport Runways 11
Fencerows (nonagricultural) 11
Firebreaks 11
Highway Rights-of-Way 12
Industrial Sites 12
Paved Surfaces 13
Railroad Rights-of-Way 13
Utility Rights-of-Way 14

AQUATIC NONFOOD CROP 14
(Aquatic Sites) 14
Ditchbanks 14

DRAFT
5/m
.05501

TEBUTHIURON*

DRAFT

TYPE PESTICIDE: Herbicide

FORMULATIONS:

Tech (95%)
G (1%, 2%, 3%, 5%)
P/T (10%, 13.8%, 15.2%, 20%, 30.5%, 40%)
WP (80%)
FlC (85%)
RTU .(0.03 lb/gal (0.36%))

GENERAL WARNINGS AND LIMITATIONS: Tebuthiuron is used in noncroplands and pasture/rangelands to control grasses, broadleaf weeds, brush and woody plants. When applied to the soil, this chemical is absorbed by the roots of plants. Effects are slow to appear and will not become apparent until sufficient moisture has carried the chemical into the root zone. Applications should be made prior to rainfall. A minimum of 1 to 1.5 inches of rainfall is required. Time required for plant control is dependent on soil type, amount of rainfall, and depth of species rooting. Some species may go through several defoliations and refoliations over a period of 1 to 3 years before dying. Use a mechanical spreader or other device which will spread the required dosage evenly over the area to be treated. Do not apply directly to lakes, ponds, or streams or contaminate water sources by cleaning of equipment or disposal of wastes. Do not apply on field crops. Do not apply when winds are gusty or to areas where soil movement by water erosion and/or natural or mechanical means is likely. Do not apply when the ground is frozen, snow covered, or saturated with water. Do not make broadcast applications where forage or maintenance of grass cover is desired. Desirable plants with feeder roots extending into treated areas may be seriously injured. Injury to most herbaceous perennials is reduced when treatment is applied when this vegetation is dormant. Do not use on prickly pear, cholla, cactus or sassafras. In areas treated with 4 pounds active ingredient or less, livestock may be allowed to graze and grass may be cut for hay 1 year after application. For band treatments, reduce dosages proportionately. Band treatments in areas of steep terrain should be applied across existing slopes to prevent soil erosion. Cut brush should be allowed to resprout to a height of 5 feet before treatment. Requires actively growing plant to be effective.

Livestock Tolerances:

Milk	0.3 ppm
Cattle (fat)	2.0 ppm
Cattle (meat)	2.0 ppm
Cattle (mbyp)	2.0 ppm
Goats (fat)	2.0 ppm
Goats (meat)	2.0 ppm
Goats (mbyp)	2.0 ppm
Horses (fat)	2.0 ppm
Horses (meat)	2.0 ppm
Horses (mbyp)	2.0 ppm
Sheep (fat)	2.0 ppm

*Graslan
Spike
N-(5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl)-N,N'-dimethylurea

DRAFT

GENERAL WARNINGS AND LIMITATIONS (continued)

Sheep (meat)	2.0 ppm
Sheep (mbyp)	2.0 ppm

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits photosynthesis.

BROADLEAF WEEDS CONTROLLED:

PDAAJBC	Alkali sida	(g)
PBFBHBA	Annual fleabane	(b)(f)
PBMADBO	Annual sedge	(b)
PBFDCBC	Annual sowthistle	(b)
PEMADAA	Bedstraw	(b)
PBFBZBA	Bitter rubberweed	(a)
PAZAJBA	Bouncingbet	(b)
PBFCRBA	Bristly oxtongue	(d)(g)
PDXABBC	Buckhorn plantain	(b)
PBMABBE	Bull sedge	(d)
PBFBSBE	Burroweed	(a)
PF A	Buttercup	(g)
PB B	Canada thistle	(f)
PBFBWBB	Camphorweed	(b)
PBZACBA	Carolina geranium	(b)
PADABBA	Carpetweed	(c)
PBFAVBA	Chickory	(c)
PAZAAAC	Chickweed	(b)(f)
PARABBB	Coast fiddleneck	(b)
PBFDQAA	Cocklebur	(b)
PBFBRBA	Common broomweed	(a)
PELAOBD	Common cinquefoil	(c)
PEUAOBD	Common mullein	(b)(f)
PEDADBA	Common purslane	(d)
PBFAEBA	Common ragweed	(a)(f)
PBFBUBA	Common sunflower	(b)
PAUADBA	Common venuslookingglass	(e)
PBVAEAA	Croton	(f)
PBFBPAA	Cudweed	(e)(g)
PBFBQBA	Curly dock	(b)
PBFBQBA	Curlycup gumweed	(b)(g)
PBFAMBA	Desert baileya	(a)
PBFBIBB	Dogfennel	(b)
PELATBD	European red raspberry	(b)
PBZABAA	Filaree	(b)
PB BA	Fivehook bassia	(g)

DRAFT

BROADLEAF WEEDS CONTROLLED (continued)

[illegible]	Giant ragweed	(b)
[illegible]	Goldenrod	(b)(f)
FKAEAA	Grape	(b)
BFAKBA	Heath aster	(b)
BFAYBA	Horseweed	(b)(f)
AYACBB	Japanese honeysuckle	(b)
BFARAA	Knapweed	(b)
EAAGAC	Knotweed	(g)
BDAIBA	Kochia	(b)
BDAEAB	Lambsquarter	(b)
DAAHAA	Mallow	(g)
BGAAAB	Morningglory	(b)
BKAAAC	Mustard	(g)
EAAGBO	Pennsylvania smartweed	(f)
BKAWAA	Pepperweed	(f)
BFBRAC	Perennial broomweed	(a)
BFDCBA	Perennial sowthistle	(c)
AAAABI	Pigweed	(b)(f)(g)
DXABAA	Plantain	(g)
FFALBA	Poison hemlock	(b)
AHABBI	Poison ivy	(c)
EMACBA	Poorjoe	(d)
BFCEBF	Prickly lettuce	(g)
DAAJBF	Prickly sida	(b)
BVAGBQ	Prostrate spurge	(c)
[illegible]	Puncturevine	(b)(g)
[illegible]	Redstem filaree	(b)
[illegible]	Ripgut brome	(b)
BFBNBA	Rosering gaillardia	(b)
BFARBI	Russian knapweed	(g)
BDAKBA	Russian thistle	(b)
BDABAA	Saltbush	(d)(g)
PBKAHBA	Shepherdspurse	(b)(g)
	Shrubby blue salvia*	
PEWAIBD	Silverleaf nightshade	(b)
PEHAGBA	Smallflower buttercup	(b)
PBFBVBB	Spikeweed	(b)
PBFCABB	Spotted catsear	(b)
PBVAGBK	Spotted spurge	(b)
PBVAGAA	Spurge	(b)(f)
PELAKAA	Strawberry	(b)
PEAAGBG	Swamp smartweed	(c)(g)
PBFBWBA	Telegraphplant	(b)(g)
PEOABBJ	Trembling aspen	(c)
PAQACBA	Trumpet creeper	(b)
PFKADBA	Virginia creeper	(b)
PBKAWBG	Virginia pepperweed	(b)
PBFAEBC	Western ragweed	(a)(g)
PBFAKBH	White heath aster	(b)
PFFANBA	Wild carrot	(b)(f)
[illegible]	Wild parsnip	(f)

DR

BROADLEAF WEEDS CONTROLLED (continued)

P[illegible]BJ	Yellow starthistle	(b)(g)
[illegible]G	Yellow woodsorrel	(f)

(a) Use 0.5 to 2.0 pounds active ingredient per acre.
(b) Use 4 pounds active ingredient per acre.
(c) Use 6 pounds active ingredient per acre.
(d) Use 8 pounds active ingredient per acre.
(e) Use 16 pounds active ingredient per acre.
(f) Use 1.7 to 2.4 pounds active ingredient per acre in areas east of the Rocky Mountains.
(g) Use 1.2 to 2.4 pounds active ingredient per acre in areas west of the Rocky Mountains.
*See Auxiliary Documentation

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCQBIBE	Alfalfa	(b)
	Allthorn*	
PCACKBA	Annual bluegrass	(b)(f)
PCABSBJ	Barley	(g)
PCABHBB	Barnyardgrass	(d)
PCAAZBA	Bermudagrass	(e)
PCQBIBB	Black medic	(b)
PCAAHBH	Broomsedge	(b)
PCAAUBA	Buffalograss	(b)
PC[illegible]AA	Bur clover	(b)
P[illegible]K	Cheat	(b)(g)
PCA[illegible]BA	Common reed	(c)
PCABRBA	Common velvetgrass	(b)
PCABFAA	Crabgrass	(d)
PCABCBA	Crowfootgrass	(b)
PCACFBC	Dallisgrass	(e)
PCAATBM	Downy brome	(b)
PCACEBD	Fall panicum	(f)
PCABMAA	Fescue	(b)
PCAAWBB	Field sandbur	(c)
PCACUAA	Foxtail	(b)(g)
PCABSBC	Foxtail barley	(c)
PCOAFBA	Henbit	(b)
PCABZBA	Italian ryegrass	(b)(g)
PCACOBA	Itchgrass	(d)
PCAATBF	Japanese brome	(c)
PCACWBC	Johnsongrass (seedling)	(d)
PCACKBD	Kentucky bluegrass	(b)(f)
PCABSBF	Little barley	(b)
PCABKAA	Lovegrass	(d)
PCQBHAA	Lupine	(b)
PCABBBA	Orchardgrass	(d)
PCAEABE	Rattail fescue	(b)
PCQBYBH	Red clover	(b)

DRAFT

TEBUTHIURON

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

PC[illegible]A	Reed canarygrass	(c)(g)
	Sacahuista*	
PCAATBE	Smooth brome	(b)
PCACEBL	Texas panicum	(b)
PCAAKAA	Threeawn	(c)
PCACIBA	Timothy	(b)
PCACFBI	Vaseygrass	(e)
PCQCAAA	Vetch	(b)
PCQBJBA	White sweetclover	(c)(f)
PCAAOBB	Wild oats	(b)(g)
PCACEBC	Witchgrass	(b)(g)

(b) Use 4 pounds active ingredient per acre.
(c) Use 6 pounds active ingredient per acre.
(d) Use 8 pounds active ingredient per acre.
(e) Use 16 pounds active ingredient per acre.
(f) Use 1.7 to 2.4 pounds active ingredient per acre in areas east of the Rocky Mountains.
(g) Use 1.2 to 2.4 pounds active ingredient per acre in areas west of the Rocky Mountains.
*See Auxiliary Documentation

WOODY PLANTS CONTROLLED:

PAPACBC	Agarito	(k)
PT[illegible]BA	Allegheny blackberry	(b)
P.[illegible]C	Alligator juniper	(k)(q)
PBWADBA	American beech	(k)
PFEAEBB	American elm	(m)
PDYABBA	American sycamore	(o)
PDMACAA	Ash	(k)(p)
PFPADBA	Ashe juniper	(k)
PDUABBA	Balsam fir	(k)
PEOABBB	Balsam poplar	(k)
PEWAFBB	Berlandier wolfberry	(m)
PBFAJBL	Big sagebrush	(a)(i)
PACABBC	Bigleaf maple	(o)
PEOABBF	Bigtooth aspen	(k)
PELAFBA	Birchleaf mountain mahogany	(k)
PELAPBF	Bitter cherry	(k)
PCKABBB	Bitternut hickory	(q)
PELAPBI	Black cherry	(k)(p)(q)
PCKABBK	Black hickory	(n)(q)
PCQBQBA	Black locust	(m)(q)
PBWAFCU	Black oak	(k)(p)
PELATBH	Black raspberry	(o)
PCOAQBE	Black sage	(m)
PELATAC	Blackberry	(p)
PCQACBG	Blackbrush acacia	(k)(p)
P[illegible]CB	Blackjack oak	(k)(p)

DRAFT

WOODY PLANTS CONTROLLED (continued)

PF[illegible]BG	Blue oak	(k)
P[illegible]A	Blueberry	(k)(q)
PE[illegible]BA	Bluewood condalia	(k)(p)(q)
PACABBD	Boxelder	(k)(p)
PAHACBB	Brazilian peppertree	(o)
PAYAEBC	Buckbrush	(k)(p)
PERABBB	Buckthorn bumelia	(k)
PBWAFCA	Bur oak	(k)(p)
PBWAFBH	California scrub oak	(k)
PCQACBF	Catclaw acacia	(k)(p)(q)
PCQBKBD	Catclaw mimosa	(h)(p)
PEUASBA	Cenzia	(h)(p)
PELACBA	Chamise	(k)
PFEAEBD	Chinese elm	(c)
PBVAJBA	Chinese tallowtree	(c)
PELAIBA	Cockspur hawthorn	(c)
PENACBC	Colima	(q)
PELAPBK	Common chokeberry	(k)
PBPABBB	Common persimmon	(q)
PEOABAA	Cottonwood	(k)(p)
PEJAFBA	Coyotillo	(k)
PFMACBA	Creosotobush	(h)(p)
PBAAEBA	Desert yaupon	(k)
PDUAIBA	Douglas-fir	(k)
PEOABBC	Eastern cottonwood	(n)
PFPADBK	Eastern redcedar	(o)(q)
PD[illegible]BC	Elbowbush	(k)
P[illegible]A	Elm	(k)
PE[illegible]BF	Evergreen blackberry	(o)
PBHABBB	Flowering dogwood	(k)(p)(q)
PBWAFBO	Gambel oak	(k)(p)(q)
PFEABBC	Granjeno	(k)
PBIACBF	Gray birch	(k)
PDMACBE	Green ash	(o)(q)
PBUACBI	Greenleaf manzanita	(c)
PBFALBB	Groundsel baccharis	(o)
PCQACBA	Guajillo	(k)(p)
PFMAEBA	Guayacan	(k)(p)(q)
PFEABAA	Hackberry	(k)(p)
PELAWBE	Hardhack	(k)
PELAIAA	Hawthorn	(k)(p)
PENACBB	Herculesclub	(p)
PCKABAA	Hickory	(p)(q)
PCQAZBA	Honeylocust	(q)
PBUAKAB	Huckleberry	(k)
PCQACBE	Huisache	(k)(p)(q)
PDUAHBB	Jack pine	(o)
PFPADAA	Juniper	(k)(p)
PCQBPBA	Kudzu	(k)
PFIAFBA	Largeleaf lantana	(o)
PAHABBF	Laurel sumac	(c)

DRAFT

WOODY PLANTS CONTROLLED (continued)

P[illegible]A	Leatherstem	(k)(p)(q)
PA[illegible]BG	Littleleaf sumac	(l)
PBWAFCV	Live oak	(k)
PCQBQAA	Locust	(p)
PEJAEBB	Lotebush condalia	(n)(p)(q)
PELASBC	Macartney rose	(k)(p)
PBUACAA	Manzanita	(k)
PACABAA	Maple	(p)(q)
PDIAFAA	Melaleuca	(o)
PCQBNBA	Mesquite	(p)(q)
PBWAFDA	Mohr oak	(h)
PELASBK	Multiflora rose	(k)(p)
	New Mexico locust*	
PDUAGBF	Norway maple	(o)
PFPADBE	Oneseeded juniper	(k)(q)
PDGACBA	Osage orange	(p)(q)
PCQANBC	Paloverde	(a)(k)(p)
PBPABAA	Persimmon	(c)
PCKABBD	Pignut hickory	(m)
PBWAFCH	Pin oak	(k)
PDUAHAA	Pine	(k)(p)
PDUAHBF	Pinyon pine	(l)
PAAAABM	Plum	(k)(p)
PBWAFCQ	Post oak	(k)(p)
PENACBA	Prickly ash	(k)
PDMAAAB	Privet	(c)
P[illegible]C	Red alder	(k)
PA[illegible]BG	Red maple	(q)
PDGADBC	Red mulberry	(k)(p)
PBWAFCN	Red oak	(k)
PDUAHBM	Red pine	(o)
PFPADBH	Redberry juniper	(k)
PFPADBI	Rocky Mountain juniper	(k)
PELASAA	Rose	(p)
PBHABBA	Roughleaf dogwood	(l)
PCTAJBD	Roundleaf greenbrier	(c)
PZAAAEN	Running live oak	(k)(p)
PBQABBB	Russian olive	(c)(k)(p)
PBFAJAB	Sagebrush	(k)(p)
PBUAEBA	Salal	(o)
PEZABBC	Saltcedar	(k)
PBFAJBG	Sand sagebrush	(a)
PBWAFBQ	Sand shimmery oak	(h)(p)
PCKABBI	Shagbark hickory	(b)
PAHABBB	Shinning sumac	(l)
PDUAHBE	Shortleaf pine	(o)
PACABBH	Silver maple	(o)(q)
PAHABBK	Skunkbush sumac	(k)(l)
PFEAEBG	Slippery elm	(c)
PEWADBA	Small datura	(k)
PA[illegible]D	Smooth sumac	(l)

DRAFT

TERRESTRIAL NONFOOD CROP

(Agricultural Crops)

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
28035AA 28045AA	Pastureland Rangeland	20.0 ppm (grasses, hay) (rangeland, forage) Do not allow lactating cows to graze on or consume hay from treated areas for 2 years after application. Do not cut forage grass for hay in treated areas for 2 years after application. General Information: Do not use in or near home sites or landscaped areas. Do not use in soils containing more than 5 percent organic matter, more than 30 percent clay, or on Blackland soils. Do not burn treated areas for at least 2 growing seasons after application. Not recommended for sites which contain more than 200 trees per acre. The use of aerial broadcast sprays are recommended in areas with high density brush infestation. A single application is effective for several years. Treated areas may be overseeded. Consult your local Range Management Specialist or other agricultural specialist for details on suitable species, seeding rates, timing, and fertilizer programs.
	0.5-4.0 (20%, 40% P/T) 001471-00109	Broadcast. Woody plant and broadleaf weed control. Use the lower dosage on coarse textured soils and the higher dosage on medium or fine textured soils or when treating deep-rooted plants. Make 1 application per year. May be applied by air.
	1-4 (20% P/T)	Broadcast. Soil surface treatment. Brush and woody plant control.
	0.5-1.0 (10% P/T) 001471-00115	Use limited to AZ, AR, CO, ID, KS, MO, MT, NM, NV, OK, OR, TX, UT, WA and WY. Broadcast. Brush control. Apply prior to seasonal rains. Use the lower dosage on coarse textured soils and the higher dosage on medium and fine textured soils or when treating deep-rooted plants. Apply once per year.
	1-4 grams a.i./ 100 sq.ft (15.2%, 30.5% P/T)	Use limited to AZ, AR, CO, ID, KS, MO, MT, NM, NV, OK, OR, TX, UT, WA and WY. Broadcast. Woody plant and thicket control. Grid pattern application. Do not use more than 2 grams active ingre-

DRAFT

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Pastureland cluster (continued)	
	dient per 100 square feet in areas receiving less than 20 inches annual rainfall.
1 gram a.i./inch of trunk diameter (15.2%, 30.5% P/T)	Use limited to AZ, AK, CO, ID, KS, MO, MT, NM, NV, OK, OR, TX, UT, WA and WY. Brush and tree control. Soil surface treatment. Apply no more than 5 grams active ingredient per inch of trunk diameter regardless of tree size. Distribute uniformly over soil surface within drip zone of each tree. For upright growing Utah juniper, apply 0.25 gram active ingredient per foot of tree height to the base of the tree trunk.
0.75-3.0 (20% P/T)	Use limited to the western United States. Broadcast. Soil surface treatment. Brush control. Distribute pellets uniformly over soil surface. May be applied by air.
1 gram a.i./inch of trunk diameter (13.8% P/T)	Drop zone application based on trunk diameter. Use this method for single stemmed species only. Apply uniformly over the soil surface within the drip zone of each tree.
0.25-0.50 gram a.i./ft of plant height (13.8% P/T)	Drop zone application based on tree height. Use this method for single or multi-stemmed trees that have a height greater than canopy diameter. Apply uniformly over the soil surface within the drip zone of each tree. For control of juniper species, use the lower dosage for plants up to 3 feet tall and the higher dosage for plants 3 to 10 feet tall. Do not use on junipers over 10 feet tall.
0.25 gram a.i./ft of canopy diameter (13.8% P/T)	Drip zone application based on canopy diameter. Use this method for single or multi-stemmed trees that have a canopy diameter greater than the tree height. Apply uniformly over the soil surface within the drip zone of each tree.
1-4 grams a.i./100 sq.ft (13.8% P/T)	Grid pattern application. For control of dense brush in thickets and multi-stemmed brush species. Use the higher dosage when treating large or deep-rooted plants growing in fine textured soils. For dosages of 1 to 4 grams active ingredient per 100 square feet, the grid spacing between pellets is 5 to 2.5 feet respectively.

DRAFT

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Pastureland cluster (continued)	
	0.13 lb a.i./1,000 sq.ft (20%, 40% P/T)	Spot treatment. Brush and vine control. Apply over the root system of brush and vine clumps.
	0.1 oz a.i./2-4 inches of trunk diameter (20%, 40% P/T)	Spot treatment based on trunk diameter. Tree control. Apply to the base of the tree.
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)	
670010A 670150A 670040A 670130A 670090A 670110A 670050A 670060A	Airport Runways Fencerows (nonagricultural) Firebreaks	
	4-16 (1%, 3%, 5% G) 001471-00104 (80% WP) 001471-00097 (85% FlC) 001471-00147	Broadcast. Annual/perennial grass and broadleaf weed control. Apply when weeds are actively growing. May be tank mixed with amitrole; atrazine; dicamba; diuron; 2,4-D; MSMA; surflan; paraquat; or simazine.
	1-6 (1%, 5% G) (20%, 40% P/T) 001471-00123 (80% WP) (85% FlC)	Broadcast or band. Soil surface treatment. Woody plant and brush control. Apply the wettable powder formulation in 15 to 150 gallons of water per acre. Band treatments should be spaced at intervals of 4 to 10 feet at a rate of 2 to 6 pounds active ingredient per acre. May be applied by air.
	1.7-2.5 (80% WP) (85% FlC)	Use limited to areas east of the Rocky Mountains treated the previous season with tebuthiuron or other residual herbicide. Broadcast. Total vegetation control. Apply prior to or just after weed emergence in 15 to 150 gallons of water per acre. Use the higher dosage in areas with more than 25 inches annual rainfall.

DRAFT

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Airport Runways cluster (continued)	
1.2-2.5 (80% WP) (85% F1C)	Use limited to areas west of the Rocky Mountains treated the previous season with tebuthiuron or other residual herbicide. Broadcast. Total vegetation control. Apply prior to or just after weed emergence in 15 to 150 gallons of water per acre. Use the higher dosage in areas with more than 24 inches annual rainfall.
0.13-0.14 lb a.i./ 1,000 sq.ft (1%, 5% G) (20%, 40% P/T)	Spot treatment. Brush and vine control. Apply over the root systems of brush and vine clumps.
0.1 lb a.i./2-4 inches of trunk diameter (1%, 5% G) or 0.1 oz a.i./2-4 inches of trunk diameter (20%, 40% P/T)	Spot treatment. Individual tree control. Apply to the base of the tree.
1-10 oz finished spray/2-4 inches of stem diameter (80% WP) (85% F1C)	Spot treatment. Woody plant control. Use the lower dosage as a low volume application, mixing 1 pound of tebuthiuron in enough water to make 1 gallon of finished spray; and the higher dosage as a high volume application, mixing 1 pound of tebuthiuron in enough water to make 10 gallons of finished spray.
[MAI] 2-4 (1%, 2% G)	Soil surface treatment. Broadcast. Apply anytime during the year. Repeat spot treatments may be necessary for deep rooted grasses. Formulated with diuron.
[MAI] 2-4 (2% G)	Soil surface treatment. Broadcast. Apply to areas treated the previous season with tebuthiuron or other residual herbicide. Apply before weeds emerge. Formulated with treflan.

DRAFT

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
/670040A	Highway Rights-of-Way	General Information: Highway Rights-of-Way include areas around guardrails, signposts, markers, and road shoulders. Refer to Airport Runway cluster for use and limitation information.
/670090A	Industrial Sites	General Information: Industrial Sites include areas around buildings, lumberyards and tank farms. Refer to Airport Runway cluster for use and limitation information.
/670110A	Paved Surfaces	General Information: Paved Surfaces include areas under asphalt and concrete pavements where no future landscaping is planned. Refer to Airport Runway cluster for use and limitation information.
/[illegible]50A	Railroad Rights-of-Way	General Information: Railroad Rights-of-Way include areas around ballast, railroad yards and roadbeds.
	4-16 (0.03 lb/gal SC/L) 001471-00111	Broadcast. Apply prior to or just after weed emergence in 40 to 535 gallons of water per acre.
	2.1-6.3 (0.03 lb/gal SC/L)	Broadcast or spot treatment. Woody plant and vine control. Do not use a broadcast spray where forage or maintenance of grass cover is desired.
	1.7-2.4 (0.03 lb/gal SC/L)	Use limited to areas east of the Rocky Mountains treated the previous season with tebuthiuron or other residual herbicide. Broadcast. Total vegetation control. Apply prior to or just after weed emergence in 40 to 535 gallons of water per acre. Use the higher dosage in areas with more than 25 inches annual rainfall.
	1.2-2.4 (0.03 lb/gal SC/L)	Use limited to areas west of the Rocky Mountains treated the previous season with tebuthiuron or other residual herbicide. Broadcast. Total vegetation control. Apply prior to or just after weed

DRAFT

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations

Railroad Rights-of-Way (continued)

emergence in 40 to 535 gallons water per acre. Use the higher dosage in areas with more than 25 inches annual rainfall.

0.5 oz a.i./1-2 inches of stem diameter (0.03 lb/gal SC/L)	Spot treatment. Woody plant and vine control.

Refer to Airport Runway cluster for additional use and limitation information.

/670060A Utility Rights-of-Way

General Information: Utility Rights-of-Way include areas around substations, transmission towers and poles. The 40 percent pelleted/tableted broadcast formulation may be applied by air (helicopter).

Refer to Airport Runway cluster for use and limitation information.

AQUATIC NONFOOD CROP

(Aquatic Sites)

/650130A Ditchbanks

General Information: Do not apply to any portion of the ditchbank that will come into direct contact with water. Do not apply on ditches used to transport irrigation or potable water.

Refer to TERRESTRIAL NONFOOD CROP, (Noncrop, Wide Area, and General Indoor/Outdoor Treatments), Airport Runway cluster, for use and limitation information.

DRAFT

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations

AERIAL AND TANK MIX APPLICATIONS

9001500
AAAAAAA

Aerial Application

— Refer to
TERRESTRIAL NONFOOD CROP
(Agricultural Crops)
Pastureland, Rangelands
(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)
Airport Runways, Fencerows (nonagricultural), Firebreaks, Highway Rights-of-Way, Industrial Sites, Paved Surfaces, Railroad Rights-of-Way, Utility Rights-of-Way

900300
AAAAAA

Tank Mix

— Refer to
TERRESTRIAL NONFOOD CROP
(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)
Airport Runways, Fencerows (nonagricultural), Firebreaks, Highway Rights-of-Way, Industrial Sites, Paved Surfaces, Railroad Rights-of-Way, Utility Rights-of-Way

AQUATIC NONFOOD CROP
(Aquatic Sites)
Ditchbanks

EPA Index to Pesticide Chemicals

DRAFT

TEBUTHIURON

Listing of Registered Pesticide Products by Formulation

[illegible]001 95% technical chemical
tebuthiuron (105501)
001471-00101

&001.0004 1% granular
tebuthiuron (105501)
001471-00104 034913-00011

tebuthiuron (105501) plus 3-(3,4-dichlorophenyl)-1,1-dimethylurea
(035505)
034913-00015

&002.0004 2% granular
tebuthiuron (105501) plus 3-(3,4-dichlorophenyl)-1,1-dimethylurea
(035505)
034913-00016

tebuthiuron (105501) plus trifluralin (036101)
001471-00139

&003.0004 3% granular
tebuthiuron (105501)
034913-00009

&005.0004 5% granular
tebuthiuron (105501)
001471-00103 034913-00010

&010.0005 10% pelleted/tableted
tebuthiuron (105501)
001471-00115

&013.8005 13.8% pelleted/tableted
tebuthiuron (105501)
001471-00129

&015.2005 15.2% pelleted/tableted
tebuthiuron (105501)
001471-00130

&020.0005 20% pelleted/tableted
tebuthiuron (105501)
001471-00109 001471-00123

&030.5005 30.5% pelleted/tableted
tebuthiuron (105501)
001471-00128

&040.0005 40% pelleted/tableted
tebuthiuron (105501)
001471-00119 001471-00124

DRAFT

TEBUTHIURON

Listing of Registered Pesticide Products by Formulation (continued)

&C[illegible]006 **80% wettable powder**
  tebuthiuron (105501)
    001471-00097

&285.0014 **85% flowable concentrate**
  tebuthiuron (105501)
    001471-00147

&200.0316 **0.36% (0.03 lb/gal) soluble concentrate/liquid**
  tebuthiuron (105501)
    001471-00111

DRAFT

EPA Index to Pesticide Chemicals

TEBUTHIURON

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
035505	diuron (ANSI)	3-(3,4-dichlorophenyl)-1,1-dimethylurea
036101	treflan	trifluralin

DRAFT

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
004401	amitrole (ANSI)	3-amino-s-triazole
080803	—	atrazine
029801	—	dicamba
030001	2,4-D	2,4-dichlorophenoxyacetic acid
035505	diuron (ANSI)	3-(3,4-dichlorophenyl)-1,1-dimethylurea
103601	glyphosate	glyphosate, isopropylamine, salt of
013803	MSMA	monosodium acid methanearsonate
104201	surflan	oryzalin
061601	paraquat	paraquat dichloride
080807	—	simazine

— Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

DRAFT

TEBUTHIURON

Auxiliary Documentation

Reg. No.	Cancellation Date
001386-00614	3/27/86

Registration number 001471-00123 contains a supplemental label claiming use of aerial applications for brush and woody plant control. There are no specific sites listed on the supplemental label. The assumption was made that this claim referred to all sites listed on the latest acceptable label. However, aerial applications in ditchbanks does not seem feasible considering the irrigation and potable water statements and has been omitted for this site.

*These pests could not be located in the EPA generated pest listing dated April, 1985. Dennis Szuhay is looking into this problem - as soon as pest codes are found they will be inserted.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.________________________ Date ______________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468
Expiration Date 5/31/86

ATTACHMENT D

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________________________

Registrant's Name: ______________________________

and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient named under FIFRA sec. 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product,.

OR

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________________________
and their registration number(s) is/are ______________________________

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA sec. 3(c)(2)(B).

Registrant's authorized representative: ______________________________
Signature

Dated: __________________

____
(Typed)